IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION NO. 1:25-CV-00368-TDS-JLW

UNITED THERAPEUTICS CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

PLAINTIFF UNITED THERAPEUTICS CORPORATION'S MEMORANDUM IN OPPOSITION TO DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S MOTION TO DISMISS, OR IN THE ALTERNATIVE, STAY OR TRANSFER

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INTRODUCTION

Liquidia, located in Morrisville, North Carolina, recently sued UTC, whose offices are in Research Triangle Park. That case was assigned to this Court. *See Liquidia Techs., Inc., v. United Therapeutics Corp.*, No. 1:25-CV-00299 (M.D.N.C. April 21, 2025). UTC filed the present case—involving a previously unasserted patent—as a related case so that the present dispute between the same two North Carolina companies would be consolidated and heard together. The patents asserted by UTC and Liquidia relate to methods of treating the same disease using the same active ingredient, and there is even overlap among the inventors, a former employee of both UTC and Liquidia. There is no basis for Liquidia to restrict UTC's right to bring suit in this district. Forcing UTC to file elsewhere while permitting Liquidia's action to move forward would create undue burden and potentially conflicting rulings.

Liquidia's Motion to Dismiss ("Motion", D.E. 28) should be denied because it lacks legal and factual support. The first-to-file rule, as well as the preclusion theories asserted, are inapplicable. UTC has never litigated this patent or these issues, and the law did not permit UTC to do so previously. Liquidia's Motion further fails because it asks the Court to consider facts that this Court found should not be considered and repeatedly asks the Court to accept conclusory arguments with little to no supporting evidence. The Court should deny the Motion.

LEGAL STANDARD

"A motion to dismiss under Rule 12(b)(6) tests the sufficiency of a complaint; importantly, it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). Federal Rule of Civil Procedure 8 requires only that a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quotations omitted). While the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level," "detailed factual allegations" are not required to satisfy the pleading requirement of Rule 8. *Id.* (citations omitted). The plaintiff's well-pleaded allegations are assumed to be true, and the complaint is viewed in the light most favorable to the plaintiff. *Mylan Lab'ys, Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993) (citations omitted).

STATEMENT OF THE FACTS

UTC markets and sells Tyvaso® (treprostinil) Inhalation Solution. D.E. 1 ¶ 2. Tyvaso® was approved by the FDA in 2009 for the treatment of pulmonary arterial hypertension ("PAH," Group 1 pulmonary hypertension) and was approved in 2021 for the treatment of pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). *Id.* For PAH and PH-ILD, UTC also markets and sells Tyvaso DPI® (treprostinil) Inhalation Powder. *Id.* Tyvaso DPI® was approved by the FDA in May 2022 for the treatment of both conditions. *Id.* ¶ 12.

Seeking to take advantage of UTC's pioneering efforts, on January 24, 2020, Liquidia submitted to FDA an application—known as a 505(b)(2) application—requesting approval for the drug product currently named Yutrepia™, a treprostinil inhalation powder, for the treatment of PAH. *Id.* ¶ 19; D.E. 29 at 2. A 505(b)(2) application allows an applicant to avoid conducting clinical trials of its own and piggyback on earlier clinical studies by others, here UTC. Thus, a 505(b)(2) application is a shortcut for approval. But there is a tradeoff. As discussed in greater detail below, a 505(b)(2) application triggers a pre-launch opportunity to litigate a subset of potentially relevant patents. Specifically, a limited set of patents can be listed in the FDA's Orange Book[1] for each particular Reference Listed Drug ("RLD") product. Tyvaso® and Tyvaso DPI® are separate products and are separately listed. Tyvaso® is an inhaled nebulized mist, while Tyvaso DPI® is an inhaled dry powder. A 505(b)(2) applicant, like Liquidia, must certify whether the patents listed in the Orange Book for the relevant RLD would be valid and infringed. This certification is known as a Paragraph IV certification. Yutrepia's™ New Drug Application ("NDA") relied on Tyvaso® as the RLD and contained Paragraph IV certifications directed to Patent No. 10,716,793 ("the '793 Patent") as well as two additional Patents listed in Orange Book for Tyvaso®. Liquidia has never relied on Tyvaso DPI® as the RLD for any application.

[1] When an NDA is approved the drug manufacturer lists the "patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted" in the FDA's A*pproved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *Eisai Co., Ltd. v. Mut. Pharm. Co., Inc.*, 2007 WL 4556958, at *1 (D.N.J. Dec. 20, 2007).

Between June and July 2020, UTC commenced Hatch-Waxman litigation on the '793 Patent and two additional patents listed in the Orange Book for Tyvaso®. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-CV-00755 (D. Del.) ("*Hatch-Waxman I*"). In August 2022, the district court issued a decision in *Hatch-Waxman I*, finding that the '793 Patent was both valid and infringed. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436, (D. Del. Aug. 31, 2022). The Federal Circuit affirmed the decision in July 2023. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360 (Fed. Cir. 2023).

In July 2023, Liquidia sent notice informing UTC that it amended its NDA, which originally included only an indication for PAH, to also include a second indication for PH-ILD. Liquidia's amended NDA maintained its reliance on Tyvaso® as the RLD. As a result, UTC filed a complaint ("*Hatch-Waxman II*") in September 2023, alleging infringement of a patent listed in the Orange Book for Tyvaso®—the '793 Patent. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-CV-00975 (D. Del.). The Complaint was later amended to include Patent No. 11,826,327 ("the '327 Patent").

Liquidia also pursued an *inter partes review* ("IPR") of the '793 Patent. *United Therapeutics Corp. v. Liquidia Techs.*, IPR2021-00406 (P.T.A.B.). The PTAB issued Final Written Decisions for the '793 Patent on July 19, 2022, and February 2, 2023. The claims of the '793 Patent were cancelled on November 12, 2024.

UTC obtained Patent No. 11,357,782 ("the '782 Patent") on June 14, 2022. The '782 Patent claims a "method of treating pulmonary hypertension" using "a powder formulation

of treprostinil … and a dry powder inhaler configured to administer a single event dose of the powder." *See, e.g.*, D.E. 1 ¶ 16. In the Notice of Allowance, the examiner explained that the "claimed method of dosing a dry powder, in at least 15 micrograms to 90 micrograms of treprostinil, delivered in 1 to 3 breaths, with at least 5 micrograms of treprostinil being inhaled per breath, wherein administration of an additional single event dose in the same manner occurs at least 3 hours later is not obvious based on the prior art as the method is not predictable." Ex. 1. Moreover, claim 8 includes pharmacokinetic limitations (*e.g.*, C_{max}) absent from any claim in the '793 patent. D.E. 1-1.

On March 28, 2025, Liquidia announced plans to launch Yutrepia™ upon the FDA's final decision on drug approval on May 24, 2025. *See* D.E. 1 ¶ 31. With Yutrepia's™ launch imminent, UTC filed a complaint for patent infringement and declaratory judgment on the '782 Patent on May 9, 2025. *See* D.E. 1.

Both Liquidia and UTC have availed themselves of North Carolina courts. Liquidia filed a patent infringement action against UTC for a Liquidia patent in this Court (*see Liquidia Techs., Inc., v. United Therapeutics Corp.*, No. 1:25-CV-00299 (M.D.N.C. April 21, 2025)). UTC filed a state court trade secret action against Liquidia and Robert Roscigno (based on the improper taking, misappropriation, and use of UTC trade secrets (*See* D.E. 4-14)). UTC also filed a state court breach of contract claim against Liquidia and Dr. Roscigno (*see United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 21-CVS-4094 (N.C. Super. Ct. Durham Cnty.)). The parties continue to litigate all three cases in this state.

ARGUMENT

I. UTC Properly Filed This Case In This District.

The rule against claim splitting and the first-filed rule require a clear overlap in the facts and actions at issue in the present case and another pending action. Liquidia has failed to show that the facts and actions asserted in *Hatch-Waxman II* are the same as those at issue in this litigation. For that reason alone, each of its arguments fail.

A. UTC's Procedure Was Proper and Does Not Amount to Claim Splitting.

Claim splitting is a discretionary, equitable doctrine intended to prevent piecemeal litigation, and can occur where "one suit is pending in federal court" and a plaintiff brings an additional action "on the same subject in the same court, against the same defendant at the same time." *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 273 F. App'x 256, 265 (4th Cir. 2008). When assessing claim splitting and "determining whether the second suit duplicates the first, the court considers (1) whether the second suit arises out of the same operative facts, and (2) whether the interests of judicial economy and avoiding vexatious litigation outweigh the plaintiff's interest in bringing the second suit." *Lewis v. Peterkin*, 2019 WL 7593349, at *2 (M.D.N.C. Nov. 22, 2019) (internal quotations omitted). Claim splitting is grounded in "one of the principles of res judicata," and thus remains subject to the same burden of proof as any other affirmative defense. *Sensormatic*, 273 F. App'x at 264. The burden of establishing alleged claim splitting is on Liquidia. *Unicolors, Inc. v. Macy's, Inc.*, 2015 WL 1020101, at *2 (C.D. Cal. Mar. 6, 2015). Liquidia has failed to carry its burden to establish that claim splitting bars UTC's claims for several reasons.

First, this case is different than the previous litigation between the parties. Liquidia agrees that for the actions to be "on the same subject," they must "arise[] out of the same transaction or series of transactions as the first claim." *Sensormatic*, 273 F. App'x. at 265; D.E. 29 at 13-14. And Liquidia only asserts claim splitting in view of *Hatch-Waxman II*. But the transactions leading to the present complaint are not the same as those that led to that case. *Hatch-Waxman II* arose from Liquidia's amendment of its NDA to add PH-ILD as an indication. The present action, however, is not Hatch-Waxman litigation, nor is it based on Liquidia's NDA or its Amended NDA. The '782 Complaint is an infringement action that was filed based on Liquidia's publicly announced "plans to imminently launch." D.E. 1 ¶ 29. These are not the same transactions, events, or operative facts.

Additionally, infringement claims based on different patents do not satisfy the same transaction requirement. *PPC Broadband, Inc. v. Corning Gilbert Inc.*, 2013 WL 6145799, at *2 (N.D.N.Y. Nov. 21, 2013). This is because "each patent establishes an independent and distinct property right, … [e]ach patent asserted raises an independent and distinct cause of action." *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996). Liquidia's bare assertion that "it is of no matter that this case involves a different patent," is legally incorrect.

Second, UTC's interests in pursuing this action outweigh any concerns implicated by claim splitting. *See Lewis*, 2019 WL 7593349, at *2. *Hatch-Waxman II* is scheduled for trial on June 23, 2025. *See* D.E. 29 at 11. The two actions are at significantly different

procedural stages, involving different patents and patent families, and there is no risk of duplication or inconsistent rulings.

UTC's inability to assert these claims in its prior actions further underscores its legitimate and substantial interest in bringing this suit now. Liquidia argues that UTC could have asserted the '782 patent in *Hatch-Waxman II*. D.E. 29 at 19-20. Not so. UTC could not have included the '782 Patent in *Hatch-Waxman I*, because it had not issued yet. Nor could UTC have included the '782 patent in *Hatch-Waxman II* because it was not, is not, and cannot be listed in the Orange Book for Tyvaso®, the RLD on which Liquidia relies. Thus, Liquidia has never provided a Paragraph IV certification regarding the '782 Patent. Without that certification, UTC could not have brought suit on the '782 Patent earlier.

Specifically, in Hatch-Waxman litigation, "a generic drug manufacturer may file an []NDA before a patent expires and, in so doing, allege non-infringement and invalidity of the patent. … [I]n that situation, the filing of the []NDA is an act of infringement." *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1326 (Fed. Cir. 2003); *see also* § 271(e)(2) ("It shall be an act of infringement to submit—an application" if it seeks approval of "a drug claimed in a patent or the use of which is claimed in a patent.").

In submitting an ANDA or a 505(b)(2) NDA before the expiration of patents covering a product, an applicant must make a "certification[] in its [A]NDA [or 505(b)(2) NDA] regarding each patent that is listed in the FDA's Orange Book for the referenced drug." *Reckitt Benckiser Pharms., Inc. v. Biodelivery Scis. Int'l, Inc.*, 2014 WL 2119822, *3 (E.D.N.C. May 20, 2014). One of these certifications is a Paragraph IV certification,

which occurs where the applicant alleges that the Orange Book listed patents are "invalid or will not be infringed[.]" 21 U.S.C. § 355(j)(2)(A)(vii) (Hatch-Waxman Act). "If the ANDA contains the [Paragraph IV] certification, the generic drug manufacturer must notify the patentee, who, if it disagrees with the certification, will then have forty-five days to sue the ANDA applicant for infringement under 35 U.S.C. § 271(e)(2)." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69 (Fed. Cir. 1997) (citing 21 U.S.C. § 355(j)(4)(B)(iii) (1994)). "Thus," due to the Paragraph IV certification, "§ 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Id.* at 1568-69; *see also* 35 U.S.C. § 271(e)(5) (granting application filer subject matter jurisdiction for declaratory judgment for Paragraph IV-certified applications "to the extent consistent with the Constitution").

For the patent owner to have jurisdiction and Article III standing to sue for infringement under § 271(e)(2), the ANDA or 505(b)(2) NDA must "contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." *Eisai*, 2007 WL 4556958, at *12.[2] This is supported by the placement of both § 271(e) and § 355(j)(2) within the context of the Hatch-Waxman Act and by portions of the Act's

[2] *See also Reckitt*, 2014 WL 2119822, at *4 (dismissing plaintiffs' § 271(e)(2) claim to its '832 patent covering sublingual film compositions where "Defendant [] indicated in its 505(b)(2) NDA that plaintiffs' Suboxone sublingual tablet, not sublingual film, is its [RLD]," and therefore "defendant did not file a Paragraph IV certification regarding the '832 patent, and thus plaintiffs' '832 patent has not been implicated in defendant's 505(b)(2) application.").

legislative history where Congress "expect[ed] that infringement actions … w[ould] only be brought in the instance described in section 271(e)(2), where a party submitting an [ANDA or 505(b)(2) NDA] certifies that a patent is invalid or non-infringed and gives the required notice of that certification to the patent owner." H.R. Rep. No. 98-857, pt. 1, at 46.

Liquidia's Yutrepia™ relied on Tyvaso®, not Tyvaso DPI®, as its RLD. Ex. 2 at 7. As a result, UTC had Hatch-Waxman jurisdiction to file suit only for patents that either were or that potentially should have been listed in the Orange Book for Tyvaso®—not those listed only for Tyvaso DPI®. The '782 Patent could not be Orange Book listed for Tyvaso® because it claims a "dry powder," and Tyvaso® is a nebulized mist product. *See* D.E. 1-1 at Claims. Liquidia's statement that "UTC could have asserted a claim based on alleged infringement of the '782 Patent in *Hatch-Waxman II*" (D.E. 29 at 14) is conclusory and unsupported.

Lastly, even if this Court were to find that UTC engaged in impermissible claim splitting (which it did not), this action should still proceed. There is a general exception to the rule against claim splitting, which applies where—as has occurred here—the first court lacks jurisdiction for the claims to proceed in one action. If "the court in the first action would clearly not have had jurisdiction to entertain the omitted theory or ground (or, having jurisdiction, would clearly have declined to exercise it as a matter of discretion), then a second action in a competent court presenting the omitted theory or ground should be held not precluded." *I.P. by Newsome v. Pierce*, 2020 WL 3405209, at *3 (E.D.N.C. June 19,

2020). Accordingly, the rule against claim splitting does not warrant dismissal or transfer of this action.

B. The First-Filed Rule Does Not Apply.

Likewise, the first-filed rule does not apply. The first-filed rule only applies when two cases are ***pending*** and the "two cases are the ***same* or *very similar***." *In re Telebrands Corp.*, 773 F. App'x 600, 602 (Fed. Cir. 2016) (emphasis added); *Zurich Am. Ins. Co. v. Covil Corp.*, 2019 WL 11250072, *2 (M.D.N.C. Aug. 28, 2019). Courts consider three factors to assess whether multiple cases are subject to the first-filed rule: "(1) the chronology of the filings, (2) the similarity of the parties involved, and (3) the similarity of the issues being raised." *Davis v. Zuccarello*, 2017 WL 2729089, at *3 (M.D.N.C. June 23, 2017). Additionally, "[a]pplication of the rule is discretionary, not mandatory," and "the decision to disregard the first-to-file rule is an equitable determination made on a case-by-case basis." *Zurich*, 2019 WL 11250072, at *2. Liquidia's motion fails because it relies on alleged overlap with a case that is no longer pending and because the issues being raised are not the same or similar.

1. Liquidia's First-Filed Argument Conflates Facts from Pending and Non-Pending Cases.

As a threshold matter, the Court should disregard Liquidia's first-filed argument because it requires the Court to consider a non-pending litigation, *Hatch-Waxman I*, in its analysis. This Court has repeatedly stated that the first-filed rule applies only where multiple actions are *pending* in different federal courts. *See, e.g.*, *Zurich*, 2019 WL 11250072, at *2 ("When similar lawsuits are pending in multiple federal courts, the Fourth

Circuit adheres to the first-filed rule.") (quotations omitted)); *Franco v. Progressive Cas. Ins. Co.*, 2024 WL 4785150, at *2 (M.D.N.C. July 31, 2024) ("[I]n the absence of an appeal, there is no pending case and the first-filed rule does not apply.").[3]

Liquidia's proposed application of the first-filed rule fails because it includes arguments relating to both *Hatch-Waxman I* (which is not pending) and *Hatch-Waxman II* (which is pending). This comingling of one pending and one non-pending case is pervasive throughout Liquidia's first-filed argument. *See* D.E. 29 at 12 (stating that "both *Hatch-Waxman I* and *Hatch-Waxman II* preceded this case," and that "UTC cannot legitimately dispute the issues in all three suits—whether Yutrepia™ infringes UTC's patents directed to the treatment of PH, including PAH and PH-ILD, using treprostinil-based dry-powder inhaled device—are similar, if not identical."). Liquidia's argument on the third factor—similarity of issues—relies on *Hatch-Waxman I's* focus on PAH. *See id. Hatch-Waxman II*, by contrast, concerns PH-ILD only. *See id.* Liquidia offers no analysis of whether the third factor is satisfied based on *Hatch-Waxman II* alone—because it is not. *Hatch-Waxman II* involves the unrelated '327 patent. Because Liquidia offers no legally sound argument satisfying the third prong of the first-filed rule—particularly without relying on *Hatch-Waxman I*—Liquidia's motion should be denied.

[3] *See also Jean-Francois v. Smithfield Foods, Inc.*, 2022 WL 17813139, at *2 (E.D.N.C. Dec. 19, 2022) ("The first-to-file rule applies in cases where 'a prior suit [is] pending in which all issues could be tried with equal facility.'") (quoting *Carbide & Carbon Chems. Corp. v. U.S. Indus. Chems., Inc.*, 140 F.2d 47, 49 (4th Cir. 1944)).

2. The Issues Are Not the Same Between the Present Case and Prior Cases.

Even if the Court were to consider Liquidia's *Hatch-Waxman I* arguments, Liquidia's first-filed argument nonetheless fails because this case and the prior cases do not involve the same or similar issues. Generally, "where two actions involving the same parties ***and identical issues are pending in different courts***, the first-filed action should be given priority and be allowed to proceed before the later action." *Beard v. United States*, 99 Fed. Cl. 147, 150 (2011) (emphasis added). Accordingly, transfer is appropriate where the overlap between the subject cases is identical, or "nearly complete." *Telebrands*, 773 F. App'x at 602; *see also In re Cinemark Holdings, Inc.*, 839 F. App'x 476, 478 (Fed. Cir. 2020) (stating that the first-to-file rule can be appropriate "where there is complete or nearly complete overlap between two cases.").

Here, there is neither complete nor nearly complete overlap because the cases involve different patents and different underlying issues—which is dispositive.

First, the '793 and '782 Patents claim distinct inventions, and Liquidia's brief lacks any serious factual analysis to the contrary. *See Kearns*, 94 F.3d at 1555 ("[E]ach patent establishes an independent and distinct property right, … [e]ach patent asserted raises an independent and distinct cause of action."). Liquidia's brief simply states that the patents are "nearly identical" and concludes, without any case law support (D.E. 29 at 12), that it "does not matter" that the two cases involve different patents for the first-filed rule to apply. Not so. Courts have emphasized that transfer under the first-filed rule requires "***far more*** than patents from the same family, same parties, and same accused products." *Netlist Inc.*

v. SK Hynix Inc., 2021 WL 2954095, at *3 (W.D. Tex. Feb. 2, 2021) (emphasis added); *see also Abbott Lab'ys v. Johnson and Johnson, Inc.*, 524 F. Supp. 2d 553, 558 (D. Del. 2007), *aff'd*, 297 F. App'x 966 (Fed. Cir. 2008) ("[I]t would not be appropriate to apply the first-filed rule to [earlier patent cases] [when] those cases involve different patents."); *APV N. Am., Inc. v. Sig Simonazzi N. Am., Inc.*, 295 F. Supp. 2d 393, 398 (D. Del. 2002) (holding inapplicable the first-filed rule where the Texas and Delaware actions were "not the same[ ] because they implicate[d] different patents").

Here, the patents are unquestionably different because they claim distinct inventions. The '793 Patent claims a single, acute administration of inhaled treprostinil (a "therapeutically effective single event dose") without any specific efficacy requirement, beyond being "therapeutically effective" by improving patient hemodynamics (measurements of blood parameters, such as pressure in the pulmonary vasculature). *See* '793 Patent, Claim 1. By contrast, the '782 Patent requires multiple doses at least three hours apart and includes a claim directed to the peak plasma concentration of drug in the blood, unlike the '793 Patent claims.

Liquidia asks this Court to disregard these differences and accept its conclusory statement that "the PTAB rejected the same arguments UTC made to obtain allowance of the '782 Patent." D.E. 29 at 12. Liquidia's request is surprising because it lacks ***any citation*** to the '782 Patent's prosecution history or the arguments allegedly rejected by the PTAB. Liquidia cannot be allowed to blindly draw conclusions without providing a shred of evidence or a citation to where that evidence could even be found. *See Enzo Biochem,*

Inc. v. Calgene, Inc., 188 F.3d 1362, 1379 (Fed. Cir. 1999) ("a party may not avoid its burden of proof by making a blanket statement that its proofs with respect to one patent apply to another and not provide a formal analysis as to why that is true.").[4] Liquidia also puts forth an unjustifiable presumption that the '782 Patent is invalid. D.E. 29 at 12 (asserting that "had the '782 Patent been put at issue in *Hatch-Waxman II*, Liquidia would have raised … the same validity questions that plagued the [] invalid '793 Patent."). Liquidia's stance completely ignores the strong legal principle that "[p]atents, like the claims within them, are independently presumed valid." *Enzo Biochem*, 188 F.3d at 1379. Neither argument undermines the substantial differences between the scope of the patents.

Second, beyond the difference in the patent claims themselves, the '782 Patent Complaint and the pending *Hatch-Waxman II* litigation cover different issues and rely on different evidence. As Liquidia admits, *Hatch-Waxman II* revolves around Liquidia's addition of PH-ILD to its ANDA. *See, e.g.* D.E. 29 at 5-6. Should UTC have attempted to include the '782 Patent in *Hatch-Waxman II*—ignoring any jurisdictional issues that would have precluded it from being able to do so—it would have involved adding additional issues and evidence because the '782 Patent would introduce an additional indication (PAH) and would require bringing in additional scientific evidence, expert

[4] Nor can Liquidia provide that evidence in reply, depriving UTC of the right to respond. *Craige v. Gov't Emps. Ins. Co.*, 408 F. Supp. 3d 673, 676-77 (M.D.N.C. 2019) (declining to consider an argument "newly lodged in [the] reply brief, in violation of this court's local rules, thus depriving [the opposing party] a fair opportunity to address it.").

reports, and damages considerations that would not have been judicially efficient, equitable, or proper.

Liquidia also ignores that this case concerns infringement of the '782 Patent, which could not be brought in a Hatch-Waxman action. As explained in detail in Section I.A, above, UTC could not have included the '782 Patent in any of the litigations to date because the RLD for Liquidia's Yutrepia™ product is Tyvaso®, not Tyvaso DPI®. Therefore, under the Hatch-Waxman Act, UTC could bring suit only on the patents included in the Orange Book for Tyvaso®, not Tyvaso DPI®.

Because the '782 Patent could not have been listed in the Orange Book for Tyvaso®, Liquidia did not submit a Paragraph IV certification for the '782 Patent, which is required before including it in a Hatch-Waxman case. Therefore, asserting the '782 Patent in the Delaware litigation would have risked dismissal on procedural grounds. *See Reckitt*, 2014 WL 2119822, at *4 (dismissing plaintiffs' patent infringement claim because "defendant did not file a Paragraph IV certification regarding the [] patent.").

This action should proceed in the Court in which UTC properly filed its Complaint. None of Liquidia's arguments justify eviscerating UTC's right to file suit in the forum of its choosing. *See Zurich*, 2019 WL 11250072, at *4 (stating that "the plaintiff's choice of forum is entitled to substantial weight." (internal quotations omitted)).

II. UTC's Claims Are Not Precluded Under Any Equitable Doctrine.

Issue preclusion, claim preclusion, and the *Kessler* doctrine all rely on overlapping legal claims. Liquidia makes no showing that the claims asserted in the *Hatch-Waxman I*

and *II* are the same as the claims asserted here, despite the fact that Liquidia bears the burden for claim and issue preclusion. *ArcelorMittal Atlantique et Lorraine v. AK Steel Corp.*, 908 F.3d 1267, 1274 (Fed. Cir. 2018). For that reason alone, each of its arguments must fail.

A. Claim Preclusion Does Not Apply Because the Present Litigation Is Based on a Different Patent than *Hatch-Waxman I* and *II*.

Liquidia's claim preclusion argument is fundamentally flawed because the analysis focuses on how this action involves the same *product* as *Hatch-Waxman I* and *II*—which is not in dispute—while ignoring that the key inquiry is whether the *cause of action* is the same.[5] The Federal Circuit, applying its own law, has defined "a cause of action by the transactional facts from which it arises," and it considers "the extent of the factual overlap between the two alleged claims at issue" by conducting an analysis of both the accused products and the patent claims. *In re PersonalWeb Techs. LLC*, 961 F.3d at 1375. It is Liquidia's burden to show that this action involves the same cause of action, which it has not done and cannot do. *See Oyster Optics, LLC v. Cisco Sys., Inc.*, 2021 WL 1530935, at *4 (E.D. Tex. Apr. 16, 2021) ("The party asserting claim preclusion has the burden of showing that the asserted patent claims in the two suits are essentially the same.").

This action, because it involves a different patent that could not have been brought in previous matters, necessarily arises out of a different cause of action than the previous

[5] Where, as here, "the question whether two causes of action for patent infringement are the same is an issue peculiar to patent law" are analyzed "under Federal Circuit law." *In re PersonalWeb Techs. LLC*, 961 F.3d 1365, 1374 (Fed. Cir. 2020).

cases. "Each patent asserted raises an independent and distinct cause of action." *Kearns*, 94 F.3d at 1555. Because different patents give rise to different causes of action, claim preclusion does not normally apply in those instances. *Id.* at 1555-56 ("Just as infringement of one patent is not a ground of liability for infringement of a different patent, so an involuntary dismissal of a suit regarding one patent is not a ground for dismissal of a different suit on a different patent."). Rather, claim preclusion applies to different patents only where the claims are "substantially the same" or not "materially different." *See ArcelorMittal*, 908 F.3d at 1274; *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1350 (Fed. Cir. 2014). Liquidia effectively ignores that this action involves a different patent than *Hatch-Waxman I* and *II*. Liquidia's Motion attempts to paint this suit as UTC's second bite at the apple when Liquidia is attempting to deprive UTC of its first.

Instead, like it does in its failed first-filed arguments, Liquidia assumes a false equivalency between the '793 and '782 Patents. But the '793 Patent is not at issue in this Action and "claim preclusion does not apply if either the accused activity or the scope of the patent claims at issue is materially different than in the prior case." *Seven Networks, LLC v. Motorola Mobility LLC*, 2022 WL 426589, at *2 (N.D. Tex. Feb. 10, 2022). Liquidia's bare assertion, without any analysis, that the claims of the '793 Patent are "extremely similar" cannot overcome the presumption that different patents give rise to different causes of action. *See* D.E. 29 at 7. Indeed, the patents are materially different. Though the '793 Patent and the '782 Patent cover the treatment of pulmonary hypertension

with treprostinil, the '793 Patent requires only one dose while the '782 Patent requires multiple doses, a dry powder inhaler, and specific pharmacokinetic results.

The cases Liquidia relies on do not save its argument. *See* D.E. 29 at 16-18. Liquidia's reliance on *Nystrom* and *Sejun* omits any reference to the fact that these cases involve the same patents in different actions—not two different patents in two different actions. *See Senju Pharm.*, 746 F.3d at 1352 (holding a reexamined patent is still the same patent); *Nystrom v. Trex Co., Inc.*, 580 F.3d 1281, 1284-85 (Fed. Cir. 2009) (same patent, different generation of the same product). Liquidia's reliance on *Simple Air* is also flawed. Although *SimpleAir* did involve different patents, there was a terminal disclaimer[6] which required that the later patents expire on the same day as the original patent. *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1163 (Fed. Cir. 2018). While not dispositive, the Federal Circuit reasoned "a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent." *Id*. at 1168. There was no terminal disclaimer here, as the '782 Patent was issued based on the claims being materially distinct from the '793 Patent. *See* Ex. 1. Liquidia thus has no basis to assert that the claims of two separately issued patents are the same.

As described in Section I.A, UTC could not have included the '782 Patent claims in *Hatch-Waxman I*. Courts have frequently declined to find that claim preclusion applied,

[6] When a patentee files a terminal disclaimer, it effectively shortens the term of a later expiring patent to overcome invalidation under obviousness type double patenting.

where there was a separately issued patent that was not asserted in the prior litigation, particularly when those claims could not have been asserted or where the damages sought in the second case were not accrued until after the first case filed. *See Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1345 (Fed. Cir. 2012); *Target Training Int'l, Ltd. v. Extended Disc N. Am., Inc.*, 645 F. App'x 1018, 1026 (Fed. Cir. 2016); *Gillig v. Nike, Inc.*, 602 F.3d 1354, 1363 (Fed. Cir. 2010). Liquidia has failed to meet its burden to show that this action arises out of the same cause of action and therefore has failed to show that claim preclusion applies.

B. Liquidia Has Failed to Show that Issue Preclusion Applies.

As with claim preclusion, the burden to show that issue preclusion applies rests with Liquidia. *See Allen v. Zurich Ins. Co.*, 667 F.2d 1162, 1166 (4th Cir. 1982). Liquidia fails to meet this burden because it again attempts to ignore that the '793 Patent is not, in fact, at issue in this action. As Liquidia acknowledges, issue preclusion requires that "the issue sought to be precluded is identical to one previously litigated." D.E. 29 at 18. Liquidia cannot meet its burden because the '782 Patent has never been litigated.

Liquidia attempts to meet its burden by claiming throughout its Motion that the '793 and '782 Patents contain "identical language." D.E. 29 at 21. Liquidia refers to Appendix A, which includes nothing more than the claim language. Liquidia makes no effort to map the language from one claim to the other or to show that there are no different limitations between the claims, which is its burden to meet. This is far different from the analysis provided by the defendant in *Allergan*—the only case that Liquidia relies on where issue

preclusion was found at the motion to dismiss stage. *Compare* D.E. 29 at 18-21, *with Allergan, Inc. v. Apotex, Inc.*, C.A. No. 1:14-cv-01028, D.E. 36, 8-13 (M.D.N.C. June 22, 2015) (Ex. 3) (providing a color-coded analysis of overlapping claim limitations) *aff'd sub nom. Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017). Liquidia also again ignores the fact that there was no terminal disclaimer for the '782 Patent—meaning that the examiner believed that the claims of the '782 Patent were patentably distinct from the '793 Patent.

Liquidia's reliance on *Ohio Williow Wood* is misplaced. D.E. 29, 19-20. *Ohio Willow Wood* was a summary judgment motion where the patentee offered no evidence to suggest that there was a material difference between the patents from the first and second actions. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1343 (Fed. Cir. 2013). Liquidia has offered no argument as to why this is relevant to a motion to dismiss. Nor has Liquidia made a persuasive effort at overcoming the most significant obstacle to their argument: that different patents mean different issues. *See also United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2022 WL 823521, at *5 (D. Del. Mar. 18, 2022), report and recommendation adopted, 2022 WL 1503923 (D. Del. May 12, 2022) ("there is no reason that such an exception [to the ordinary requirements of issue preclusion] would apply to a case like this, where different patents are asserted in the district court than were at issue in the IPR.").

Liquidia has failed to meet its burden the show that identical issues were involved in the prior and current action and therefore has failed to show that issue preclusion applies.

C. Liquidia Has Failed to Show that the *Kessler* Doctrine Applies.

The *Kessler* doctrine applies only to cases involving different patents when their claims are not patently distinct; it does not apply more broadly than other preclusion doctrines. *See SimpleAir, Inc.*, 884 F.3d at 1170. As such, for the reasons stated above for claim preclusion and issue preclusion, the *Kessler* doctrine claims must also fail. Further, Liquidia offers nothing more than a threadbare, unsupported statement that the claims of the '793 Patent and the '782 Patent are patently indistinct. Even ignoring the issues discussed above, this is insufficient.

As with the other preclusion doctrines, much of the case law that Liquidia cites is inapposite and ignores that the issue here does not revolve around the same set of patents. *See generally, In re PersonalWeb Techs. LLC*, 961 F.3d at 1374; *SpeedTrack, Inc. v. Office Depot, Inc.*, 791 F.3d 1317 (Fed. Cir. 2015); *Brain Life, LLC v. Elekta Inc.*, 746 F.3d 1045 (Fed. Cir. 2014). The only case that Liquidia relies on that involves different patents is *SimpleAir*, which is distinguishable because the Federal Circuit's analysis of whether there was a common cause of action focused on the terminal disclaimer between the patents in the two suits as being "very relevant to that inquiry." *SimpleAir, Inc.*, 884 F.3d at 1168. There is no terminal disclaimer between the '793 and'782 Patents to affect the analysis here. Further, courts have refused to apply the Kessler doctrine to suits involving different patents. *See, e.g., Provisur Techs., Inc. v. Weber, Inc.*, 2022 WL 202956, at *3 (W.D. Mo. Jan. 21, 2022).

Liquidia has failed to meet its burden to show that the *Kessler* doctrine applies.

CONCLUSION

For the foregoing reasons, UTC respectfully requests that the Court deny Liquidia's Motion.

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Dated: June 5, 2025

SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, L.L.P.

/s/ *Christopher G. Smith*
Christopher G. Smith
N.C. State Bar No. 22767
David A. Pasley
N.C. State Bar No. 52332
Post Office Box 2611
Raleigh, North Carolina 27602-2611
Telephone: (919) 821-6745
Email: csmith@smithlaw.com
dpasley@smithlaw.com

William C. Jackson
D.C. Bar. No. 475200
Goodwin Procter LLP
1900 N Street, NW
Washington, DC 20001
Telephone: (202) 346-4000
Email:
WJackson@goodwinlaw.com

Eric T. Romeo
MA Bar No. 691591
Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Telephone: (617) 570-1000
Email: eromeo@goodwinlaw.com

Gabriel B. Ferrante
N.Y. Bar No. 5855487
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Telephone: (212) 813-8800
Email: gferrante@goodwinlaw.com

Douglas H. Carsten
CA Bar No. 198467
Art Dykhuis
CA Bar No. 302345
McDermott Will & Emery LLP
12636 High Bluff Drive, Suite 325
San Diego, CA 92130
Telephone: (619) 467-1802
Email: dcarsten@mwe.com
adykhuis@mwe.com

Adam W. Burrowbridge
D.C. Bar No. 1001783
Timothy M. Dunker
D.C. Bar No. 1738375
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8797
Email: aburrowbridge@mwe.com
tdunker@mwe.com

Attorneys for United Therapeutics Corporation

CERTIFICATE OF WORD COUNT

The undersigned certifies that this brief is in compliance with Rule 7.3(d)(1) of the Local Rules for the Middle District of North Carolina, in that it contains less than 6,250 words, excluding the portions of the brief covered by Local Rule 7.3(d).

Dated: June 5, 2025

/s/ *Christopher G. Smith*

Christopher G. Smith
N.C. State Bar No. 22767
SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, L.L.P.
Post Office Box 2611
Raleigh, North Carolina 27602-2611
Telephone: (919) 821-6745
Email: csmith@smithlaw.com

Attorneys for United Therapeutics Corporation

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed with the Court using the CM/ECF system, which electronically served all counsel of record.

Dated: June 5, 2025

/s/ *Christopher G. Smith*
Christopher G. Smith
N.C. State Bar No. 22767
SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, L.L.P.
Post Office Box 2611
Raleigh, North Carolina 27602-2611
Telephone: (919) 821-6745
Email: csmith@smithlaw.com

Attorney for United Therapeutics Corporation